



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1759-N]

#### Medicare Program; Town Hall Meeting on the FY 2023 Applications for New Medical Services and Technologies Add-On Payments

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces a Town Hall Meeting in accordance with the Social Security Act (the Act) to discuss fiscal year (FY) 2023 applications for add-on payments for new medical services and technologies under the hospital inpatient prospective payment system (IPPS). The United States is responding to an outbreak of respiratory disease caused by the virus “SARS-CoV-2” and the disease it causes “coronavirus disease 2019” (abbreviated “COVID-19”). Due to the COVID-19 pandemic, the Town Hall Meeting will be held virtually rather than as an in-person meeting. Interested parties are invited to this meeting to present their comments, recommendations, and data regarding whether the FY 2023 new medical services and technologies applications meet the substantial clinical improvement criterion.

**DATES:** Meeting dates: The Town Hall Meeting announced in this notice will be held virtually on Tuesday, December 14, 2021 and Wednesday, December 15, 2021 (the number of new technology applications submitted will determine if a second day for the meeting is necessary; see the SUPPLEMENTARY INFORMATION section for details regarding the second day of the meeting and the posting of the preliminary meeting agenda). The Town Hall Meeting will begin each day at 9 a.m. Eastern Standard Time (e.s.t.) and check-in via online platform will begin at 8:30 a.m. e.s.t.

Deadline for requesting special accommodations: The deadline to submit requests for special accommodations is 5 p.m., e.s.t. on Monday, November 22, 2021.

Deadline for registration of presenters at the Town Hall Meeting: The deadline to register to present at the Town Hall Meeting is 5 p.m., e.s.t. on Monday, November 22, 2021.

Deadline for submission of agenda item(s) or written comments for the Town Hall Meeting: Written comments and agenda items (public comments to be delivered at the Town Hall Meeting) for discussion at the Town Hall Meeting, including agenda items by presenters (presentation slide decks), must be received by 5 p.m. e.s.t. on Monday, November 29, 2021.

Deadline for submission of written comments after the Town Hall Meeting for consideration in the Fiscal Year (FY) 2023 Hospital Inpatient Prospective Payment System/Long Term Care PPS (IPPS/LTCH PPS) proposed rule: Individuals may submit written comments after the Town Hall Meeting, as specified in the **ADDRESSES** section of this notice, on whether the service or technology represents a substantial clinical improvement. These comments must be received by 5 p.m. e.s.t. on Monday, December 27, 2021, for consideration in the FY 2023 IPPS/LTCH PPS proposed rule.

**ADDRESSES:** Meeting location: The Town Hall Meeting will be held virtually via live stream technology or webinar and listen-only via toll-free teleconference. Live stream or webinar and teleconference dial-in information will be provided through an upcoming listserv notice and will appear on the final meeting agenda, which will be posted on the New Technology website when available at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html>. Continue to check the website for updates.

Registration and special accommodations: Individuals wishing to present at the meeting must follow the instructions located in section III. of this notice. Individuals who need special accommodations should send an email to [newtech@cms.hhs.gov](mailto:newtech@cms.hhs.gov).

Submission of agenda item(s) or written comments for the Town Hall Meeting: Each presenter must submit an agenda item(s) regarding whether a FY 2023 application meets the substantial clinical improvement criterion. Agenda items, written comments, questions or other statements must not exceed three single-spaced typed pages and may be sent via email to [newtech@cms.hhs.gov](mailto:newtech@cms.hhs.gov).

**FOR FURTHER INFORMATION CONTACT:** Michelle Joshua, (410) 786-6050, [michelle.joshua@cms.hhs.gov](mailto:michelle.joshua@cms.hhs.gov) or [newtech@cms.hhs.gov](mailto:newtech@cms.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background on the Add-On Payments for New Medical Services and Technologies under the IPPS**

Sections 1886(d)(5)(K) and (L) of the Social Security Act (the Act) require the Secretary to establish a process of identifying and ensuring adequate payments to acute care hospitals for new medical services and technologies under Medicare. Effective for discharges beginning on or after October 1, 2001, section 1886(d)(5)(K)(i) of the Act requires the Secretary to establish (after notice and opportunity for public comment) a mechanism to recognize the costs of new services and technologies under the hospital inpatient prospective payment system (IPPS). In addition, section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered "new" if it meets criteria established by the Secretary (after notice and opportunity for public comment). (See the fiscal year (FY) 2002 IPPS proposed rule (66 FR 22693, May 4, 2001) and final rule (66 FR 46912, September 7, 2001) for a more detailed discussion.)

As finalized in the FY 2020 IPPS/LTCH PPS final rule, technologies which are eligible for the alternative new technology pathway for transformative new devices or the

alternative new technology pathway for Qualified Infectious Disease Products (QIDPs) do not need to meet the requirement under 42 CFR 412.87(b)(1) that the technology represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. These medical devices or products will also be considered new and not substantially similar to an existing technology for purposes of new technology add-on payment under the IPPS. (See the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) for additional information.)

As finalized in the FY 2021 IPPS/LTCH final rule, we expanded our alternative new technology add-on payment pathway to include products approved through FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway). Under this policy, for applications received for consideration of new technology add-on payments for FY 2022 and subsequent fiscal years, if an antimicrobial product is approved through FDA's LPAD pathway, it will be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under current policy, a new technology must receive FDA marketing authorization by July 1 to be considered in the IPPS final rule in order to allow complete review and consideration of all the information to determine if the technology meets the new technology add-on payment criteria at the beginning of the fiscal year (that is, October 1<sup>st</sup>).

Under the previously described policy, cases involving eligible antimicrobial products could begin receiving the new technology add-on payment sooner, effective for discharges the quarter after the date of FDA marketing authorization provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year

for which the applicant applied for new technology add-on payments. (See the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) for additional information.)

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42289 through 42292), we codified in our regulations at § 412.87 the following aspects of how we evaluate substantial clinical improvement for purposes of new technology add-on payments under the IPPS in order to determine if a new technology meets the substantial clinical improvement requirement:

- The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

- A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries means--

- ++ The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;

- ++ The new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient; or

- ++ The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the following:

-- A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication.

-- A decreased rate of at least one subsequent diagnostic or therapeutic intervention (for example, due to reduced rate of recurrence of the disease process).

-- A decreased number of future hospitalizations or physician visits.

-- A more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; an improvement in one or more activities of daily living; an improved quality of life; or, a demonstrated greater medication adherence or compliance.

++ The totality of the circumstances otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

- Evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries: Clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

- The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.

- The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

Section 1886(d)(5)(K)(viii) of the Act requires that as part of the process for evaluating new medical services and technology applications, the Secretary shall do the following:

- Provide for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries before publication of a proposed rule.
- Make public and periodically update a list of all the services and technologies for which an application is pending.
- Accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial improvement.
- Provide for a meeting at which organizations representing hospitals, physicians, manufacturers and any other interested party may present comments, recommendations, and data to the clinical staff of CMS as to whether the service or technology represents a substantial improvement before publication of a proposed rule.

The opinions and presentations provided during this meeting will assist us as we evaluate the new medical services and technology applications for FY 2023. In addition, they will help us to evaluate our policy on the IPPS new technology add-on payment process before the publication of the FY 2023 IPPS proposed rule.

## **II. Town Hall Meeting Format and Conference Call/Live Streaming Information**

### **A. Format of the Town Hall Meeting**

As noted in section I. of this notice, we are required to provide for a meeting at which organizations representing hospitals, physicians, manufacturers and any other interested party may present comments, recommendations, and data to the clinical staff of CMS concerning whether the service or technology represents a substantial clinical improvement. This meeting will allow for a discussion of the substantial clinical improvement criterion for the FY 2023 new medical services and technology add-on

payment applications. Information regarding the applications can be found on our Web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html>.

The majority of the meeting will be reserved for presentations of comments, recommendations, and data from registered presenters. The time for each presenter's comments will be approximately 10 to 15 minutes and will be based on the number of registered presenters. Individuals who would like to present must register and submit their agenda item(s) via email to [newtech@cms.hhs.gov](mailto:newtech@cms.hhs.gov) by the date specified in the **DATES** section of this notice.

Depending on the number of applications received, we will determine if a second meeting day is necessary. A preliminary agenda will be posted on the CMS website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html> by November 22, 2021, to inform the public of the number of days of the meeting.

In addition, written comments will also be accepted and presented at the meeting if they are received via email to [newtech@cms.hhs.gov](mailto:newtech@cms.hhs.gov) by the date specified in the **DATES** section of this notice. Written comments may also be submitted after the meeting for our consideration. If the comments are to be considered before the publication of the FY 2023 IPPS proposed rule, the comments must be received via email to [newtech@cms.hhs.gov](mailto:newtech@cms.hhs.gov) by the date specified in the **DATES** section of this notice.

#### B. Conference Call, Live Streaming, and Webinar Information

As noted previously, the Town Hall Meeting will be held virtually due to the COVID-19 pandemic. There will be an option to participate in the Town Hall Meeting via live streaming technology or webinar and a toll-free teleconference phone line. Information on the option to participate via live streaming technology or webinar and a teleconference dial-in will be provided through an upcoming listserv notice and will



appear on the final meeting agenda, which will be posted on the New Technology website at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html>. Continue to check the web site for updates.

#### C. Disclaimer

We cannot guarantee reliability for live streaming technology or a webinar.

### **III. Registration Instructions**

The Division of New Technology in CMS is coordinating the meeting registration for the Town Hall Meeting on substantial clinical improvement. While there is no registration fee, individuals planning to present at the Town Hall Meeting must register to present.

Registration for presenters may be completed by sending an email to [newtech@cms.hhs.gov](mailto:newtech@cms.hhs.gov). Please include your name, address, telephone number, email address and fax number.

Registration for attendees not presenting at the meeting is not required.

### **IV. Collection of Information**

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

**Dated:** September 21, 2021

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**Lynette Wilson,**

Federal Register Liaison,

Centers for Medicare & Medicaid Services.

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